NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

LENOARD COTTRELL, *et al.*, Plaintiffs, v. ALCON LABORATORIES, INC., *et al.*, Defendants.	:	Civ. Action No.: 14-5859(FLW) **OPINION**

WOLFSON, District Judge:

In this putative consumer class action, in- and out-of-state plaintiffs[1] accuse defendant pharmaceutical manufacturers and distributors[2] of engaging in unfair and illegal business practices

[1] These plaintiffs include: Leonard Cottrell, Sandra Henon, William Reeves, George Herman, Simon Nazzal, Carol Freburger, Jack Liggett, Patricia Bough, Mack Brown, Dolores Gillespie, Deborah Harrington, Robert Ingino, Edward Rogers, Jr., Deborah Rusignulolo, Dorothy Stokes, Josephine Troccoli, Hurie Whitfield, Thomas Layloff, Carolyn Tanner, Patsy Tate, John Sutton, Jesus Renteria, Glendelia Franco and Nadine Lampkin (collectively, "Plaintiffs").

[2] Plaintiffs name as defendants both brand-name and generic pharmaceutical manufacturers and their distributors. The brand name companies include: Alcon Laboratories, Inc., Alcon Research, Ltd., Allergan, Inc., Allergan USA, Inc., Allergan Sales, LLC, Pfizer Inc., Valeant Pharmaceuticals International, Inc., Bausch & Lomb, Inc., Aton Pharma, Inc., Merck & Co., Inc., and Merck, Sharpe & Dohme Corp. (collectively, the "Brand Name Defendants"). The generic companies are Falcon Pharmaceuticals, Ltd., Sandoz Inc., Prasco LLC, Akorn, Inc. (collectively, the "Generic Defendants"). All defendants will be collectively referred to as "Defendants."

Exhibit B

by marketing prescription eye medications that allegedly deliver unnecessarily large eye drops, which results in consumers purchasing more medication than they require. These Plaintiffs have brought various state law consumer fraud-related claims against Defendants. The Generic and Brand Name Defendants move separately to dismiss Plaintiffs' Complaint on the following grounds: (1) lack of standing; (2) preemption; and (3) failure to state a claim. For the reasons set forth herein, the Court **GRANTS** Defendants' motions on the basis that Plaintiffs lack standing to bring suit, and therefore, all of Plaintiffs' claims are dismissed without prejudice. However, Plaintiffs are given leave to amend their Complaint within thirty-days (30) from the date of the Order accompanying this Opinion.

BACKGROUND

For the purposes of these motions, I will only recount relevant facts from Plaintiffs' Complaint and take them as true. Defendants are brand name and generic pharmaceutical companies that "perform selling, marketing and distribution activities . . . for [various] prescription eye drop products." Compl., ¶ 43. These eye drops, also known as "topical ophthalmic pharmaceuticals," are prescribed for serious diseases and conditions such as glaucoma, allergies, infections, inflammations, [and] pre- and post-operative conditions . . . ." *Id.* at ¶ 2. Defendants "sell their prescription eye drop products as fluid in

plastic bottles. They sell a given volume of medication (*e.g.*, 2.5 or 5.0 mL) for a certain price." *Id.* at ¶ 3.

According to Plaintiffs, scientific literature from the past decades "establishes that these bottles, which also serve as dispensers, emit drops so large that they exceed the capacity of the fornix, the area between the eye and the lower eyelid." *Id.* at ¶ 5. Consequently, the excess fluid "can cause allergy or pigmentation, or drains into their nasolacrimal drainage systems and from there into the bloodstream where it can create a risk of toxic side effects." *Id.* Plaintiffs submit that, according to certain scientific studies, "[s]maller size drops on the order of 15 µL have an efficacy and bioavailability equivalent to larger drops." *Id.* at ¶ 8. "Yet Defendants' eye drops are uniformly much larger than 15 µL. Some are more than three times that size." *Id.* at ¶ 9. Plaintiffs allege that as a result of Defendants' design, "the excess product cannot be used, is entirely wasted, [and] provides no pharmaceutical benefit." *Id.* at ¶ 5.

Indeed, the gravamen of Plaintiffs' Complaint is that "Defendants have persisted in their unfair, unethical, unconscionable, and unlawful practices of selling prescription ophthalmic medicine in dispensers that emit much larger eye drops. As a result, consumers use more medication than they should, run out of medicine before they should, and have to buy additional bottles at great expense, providing increased . . . profits for

Defendants." *Id.* at ¶ 11. In that regard, Plaintiffs complain that "there is no legitimate reason why Defendants have not supplied smaller eye drops. As they have long known, the size of the drop is determined by a factor under their control, the dimensions of the plastic dropper tip." *Id.* at ¶ 10. Instead, Plaintiffs claim that Defendants "would not reduce the drop size of [their] products because it would mean that patients would be able to use the bottles longer and [Defendants] would therefore sell less product." *Id.* at ¶ 6. Importantly, as to damages, Plaintiffs base their claims on the allegation that "patients are entitled to receive full use and therapeutic benefit of the entire product they purchase. Yet because of the Defendants' illegal schemes to increase their profits at consumers' expense, patients are compelled to purchase larger quantities that, through no fault of their own, go to waste, and as a result they and their third-party payor pay much more than they should for the treatment they need." *Id.* at ¶ 3.

Plaintiffs further allege certain facts regarding the role of the Food and Drug Administration ("FDA") in approving the size of eye drops. Plaintiffs aver that "a reduction in eye drop size to 15 µl would not have a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug product as these factors may relate to the safety or effectiveness of the drug product." *Id.* at ¶ 153. Therefore,

Plaintiffs, in their Complaint, claim that a reduction in eye drop size would not be a "major change" requiring prior FDA approval. *See Id.* Moreover, Plaintiffs explain that because the FDA does not "regulate the economics of drug use . . . the FDA does not require or specifically permit Defendants [] to make their eye drops so large that it leads to waste of medication." *Id.* at ¶ 155. In further support of their position that the FDA plays no role in this respect, Plaintiffs cite to certain anecdotal evidence. For example, Plaintiffs point out that defendant Alcon's drug, Travatan Z, had a 25 µL when the FDA conducted its initial approval review. *Id.* at ¶ 156. Nevertheless, Plaintiffs allege that just a few years later, a scientific study determined that "the size of Travatan Z drops [was] 30 µL." *Id.* at ¶ 157. And, according to Plaintiffs, "the FDA's website contains no applications for, or approvals of, the above changes in drop size . . . . Thus, [the] FDA approval of those changes was apparently not required." *Id.* at ¶ 158.

In the Complaint, twenty-five causes of action are asserted against Defendants. Plaintiffs seek to bring these claims individually, and on behalf of classes of consumers and third-party payors who have paid all or part of the purchase prices of prescription eye drops manufactured and sold by Defendants. More specifically, each of the named plaintiffs asserts consumer fraud related claims applicable in the state in which he/she resides.

Those state laws include: New Jersey Consumer Fraud Act, California Unfair Competition Law, Florida Deceptive and Unfair Trade Practices Act, Illinois Consumer Fraud Act, North Carolina Unfair and Deceptive Trade Practices Act and Texas Deceptive Trade Practices Act.

On these current motions, the Brand Name and Generic Defendants move separately to dismiss all of Plaintiffs' claims based on standing, preemption and failure to state a claim.[3] Because standing is a threshold question of jurisdiction, I turn to that issue first. *See Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 109-10 (1998) (finding that a plaintiff's Article III standing is a prerequisite for the federal courts to decide the merits of a suit); *Ballentine v. United States*, 486 F.3d 806, 810 (3d Cir. 2007).

[3] To date, similar claims against Defendants have been brought in three other federal jurisdictions: Florida, Missouri, and Illinois. In the Florida action, *Freburger v. Alcon Labs.*, No. 13-24446 (S.D. Fla.), plaintiffs voluntarily dismissed the lawsuit before oral argument on a pending motion to dismiss. In the Illinois case, *Eike v. Allergan, Inc.*, No. 12-1141 (S.D. Ill.), the court there denied defendants' motion to dismiss based on similar grounds to those asserted here. However, the district court in the Eastern District of Missouri dismissed plaintiffs' claims on identical arguments raised by Defendants in this matter. *See Thompson v. Allergan USA, Inc.*, 993 F. Supp. 2d 1007 (E.D. Mo. 2014),

DISCUSSION

I. Standing

Article III of the Constitution limits the scope of the federal judicial power to the adjudication of "cases" or "controversies." U.S. Const. art. III, § 2. This "bedrock requirement," *see Valley Forge Christian Coll. v. Ams. United for Separation of Church & State, Inc.*, 454 U.S. 464, 471 (1982), protects the system of separation of powers and respect for the coequal branches by restricting the province of the judiciary to "decid[ing] on the rights of individuals." *Marbury v. Madison*, 5 U.S. 137 (1803). Indeed, "'[n]o principle is more fundamental to the judiciary's proper role in our system of government than the constitutional limitation of federal-court jurisdiction to actual cases or controversies.'" *Raines v. Byrd*, 521 U.S. 811, 818 (1997) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 37 (1976)).

Courts have developed several justicability doctrines to enforce the case-or-controversy requirement, and "perhaps the most important of these doctrines" is the requirement that "a litigant have 'standing' to invoke the power of a federal court." *In re Schering-Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 244 (3d Cir. 2012)(quoting *Allen v. Wright*, 468 U.S. 737, 750 (1984)). The seminal standing question is "whether the plaintiff has alleged such a personal stake in the outcome of the

controversy as to warrant his [or her] invocation of federal-court jurisdiction and to justify exercise of the court's remedial powers on his [or her] behalf." *Id.* (internal quotations and citations omitted).

Of course, a plaintiff bears the burden of meeting the "irreducible constitutional minimum" of Article III standing by establishing three well-settled elements:

> First, the plaintiff must have suffered an injury in fact—an invasion of a legally protected interest which is (a) concrete and particularized and (b) actual or imminent, not conjectural or hypothetical.
>
> Second, there must be a causal connection between the injury and the conduct complained of—the injury has to be fairly traceable to the challenged action of the defendant, and not the result of the independent action of some third party not before the court.
>
> Third, it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.

Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992) (internal quotations, alterations, and citations omitted).

The Third Circuit has stressed that of the three required elements of constitutional standing, "the injury-in-fact element is often determinative." *Toll Bros., Inc. v. Twp. of Readington*, 555 F.3d 131, 138 (3d Cir. 2009). To satisfy this requirement, the alleged injury must be "particularized," such that it "must affect the plaintiff in a personal and individual way." *Lujan*, 504 U.S. at 560 n.1. Indeed, an injury-in-fact also "must be concrete

in both a qualitative and temporal sense. The complainant must allege an injury to himself that is distinct and palpable." *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990). And, the injury must not be abstract or subjective. *See Id.*; *Laird v. Tatum*, 408 U.S. 1, 13-14 (1972). Allegations of a potential future injury, or the mere possibility of a future injury, will not establish standing. *See Whitmore*, 495 U.S. at 158; *Employer's Ass'n of New Jersey v. New Jersey*, 601 F. Supp. 232, 238 (D.N.J. 2003), aff'd 774 F.2d 1151 (3d Cir. 1985). While economic injury is one of the paradigmatic forms of standing, *see Danvers Motor Co., Inc. v. Ford Motor Co.*, 432 F.3d 286, 291 (3d Cir. 2005), a demand for damages, by itself, will not establish an injury-in-fact. *See Rivera v. Wyeth-Ayerst*, 283 F.3d 315, 320 (5th Cir. 2002); *Koronthaly v. L'Oreal USA, Inc.*, No. 07-5588, 2008 U.S. Dist. LEXIS 59024, at *13 (D.N.J. Jul. 29, 2008).

Moreover, "the 'injury-in-fact' test requires more than an injury to a cognizable interest. It requires that the party seeking review be himself [or herself] among the injured." *Id.* at 563 (quoting *Sierra Club v. Morton*, 405 U.S. 727, 734-35 (1972)). The injury must also be "an invasion of a legally protected interest." *Id.* at 560. In other words, the injury-in-fact requirement exists to assure that litigants have a "personal stake" in the litigation. *See The Pitt News v. Fisher*, 215 F.3d 354, 360 (3d Cir. 2000). By ensuring that litigants present actual cases and controversies,

courts can keep the judicial branch from encroaching on legislative prerogatives, thereby preserving the separation of powers. *See Valley Forge v. Americans United for Separation of Church and State*, 454 U.S. 464, 473-74 (1982).

"[T]he standing inquiry requires careful judicial examination of a complaint's allegations to ascertain whether the particular plaintiff is entitled to an adjudication of the particular claims asserted." *Allen*, 468 U.S. at 752. In that regard, at the pleading stage, "[a]lthough general factual allegations of injury resulting from the defendant's conduct may suffice, the complaint must still 'clearly and specifically set forth facts sufficient to satisfy' Article III." *Reilly v. Ceridian Corp.*, 664 F.3d 38, 41 (3d Cir. 2011) (quoting *Lujan*, 504 U.S. at 561); *Whitmore*, 495 U.S. at 155; *see, e.g., Anjelino v. N.Y. Times Co.*, 200 F.3d 73, 88 (3d Cir. 2000) ("Standing is established at the pleading stage by setting forth specific facts that indicate that the party has been injured in fact or that injury is imminent, that the challenged action is causally connected to the actual or imminent injury, and that the injury may be redressed by the cause of action.").

In this case, although Plaintiffs assert numerous claims and allege a variety of scientific studies relating to the designs of Defendants' eye drop bottles, their only theory of economic harm is relatively straightforward: Plaintiffs were injured because they did not receive the full use and therapeutic benefit of the

entire product they purchased due to Defendants' design of their bottles to dispense larger than necessary eye drops, which led to waste. Simply stated, Plaintiffs maintain that their losses resulted from overpaying for wasted drops that they were not able to use. Moreover, while Plaintiffs allege that physical harm can result from an excessive dose of the medications, none of the named Plaintiffs have alleged that they suffered any side effects from the use of the eye drops. Thus, Plaintiffs, themselves, may not premise standing on a theory of physical injury.

Defendants posit that Plaintiffs have not shown a concrete injury-in-fact because Plaintiffs received the benefit of their bargain; that is, Plaintiffs were able to use the prescribed eye medications that they purchased. Plaintiffs, in response, contend that standing is easily established in this case based on the standards set forth by § 5(a) of the Federal Trade Commission ("FTC") Act. Plaintiffs' argument relies on a FTC statement, entitled "Policy Statement on Unfairness" ("Policy Statement"). Pursuant to the Policy Statement, "[a]n act or practice [in the context of consumer fairness] is 'unfair' . . . if it causes or is likely to cause substantial injury to consumers which is not reasonably avoidable by consumers themselves and not outweighed by countervailing benefits to consumers or competition." *See* FTC

Policy Statement on Unfairness (Dec. 17, 1980).[4] Substantial injury, according to the Policy Statement, may involve "monetary harm . . . when sellers coerce consumers into purchasing unwanted goods and services." *Id.* Based on these standards, Plaintiffs allege, in part, that "Defendants' practices cause substantial consumer injury because Defendants have . . . [compelled] consumers into purchasing unwanted amounts of prescription eye drops." Compl., ¶ 189. The Court does not find Plaintiffs' theory of economic damages sufficient to confer standing.

At the outset, while Plaintiffs rely on standards set forth in the Policy Statement, an alleged violation of the Policy Statement, by itself, is not sufficient to show an injury-in-fact for standing purposes. *See Polanco v. Omnicell, Inc.*, 988 F. Supp. 2d 451, 469 (D.N.J. 2013) ("merely asserting violations of certain statutes is not sufficient to demonstrate an injury-in-fact for purposes of establishing standing under Article III . . . ."); *Doe v. Nat'l Bd. of Med. Exam'rs*, 199 F.3d 146, 153 (3d Cir. 1999) (observing that it is "incorrect" to "equate[] a violation of a statute with an injury sufficient to confer standing" and

[4] Plaintiffs argue that the Policy Statement is critical to the standing analysis because they have based their claims in large part on the standards set forth in the Policy Statement, which certain states -- namely, Florida, Illinois and North Carolina -- have adopted as a part of their consumer fraud statutes. *See* Compl., ¶¶ 210, 216, 220(citing Fla. Stat. § 501.204(2); 815 ILCS 505/2; N.C.G.S. § 75-1.1(a)).

explaining that "[t]he proper analysis of standing focuses on whether the plaintiff suffered an actual injury, not on whether a statute was violated."); *see also Rivera v. Wyeth-Ayerst Laboratories*, 283 F.3d 315, 319-20 (5th Cir. 2002) (finding that plaintiffs could not prevail by establishing that Wyeth violated a legal duty owed to consumers; instead, the injury must be personal). Rather, each Plaintiff must allege that he or she personally suffered some actual economic damage as a result of using Defendants' medications.

There are typically two theories of economic harm associated with consumer fraud actions: benefit-of-the-bargain and out-of-pocket expenses. The former relates to economic damages caused by a product failing to perform as advertised, and therefore, the consumer would not have received the benefit of his/her bargain. *See, e.g., Koronthaly v. L'Oreal USA, Inc.*, 374 Fed. Appx. 257, 259 (3d Cir. 2010) ("[a]bsent any allegation that [plaintiff] received a product that failed to work for its intended purpose or was worth objectively less than what one could reasonably expect, [plaintiff] has not demonstrated a concrete injury-in-fact."). The latter encompasses any expenses that a plaintiff incurred as a result of purchasing the defective product, *e.g.*, replacement costs. *See, e.g., Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 606 (3d Cir. 2012); *Dicuio v. Brother Intern. Corp.*, No. 11-1447, 2012 U.S. Dist. LEXIS 112047, at *7 (D.N.J. Aug. 9, 2012) ("The

out-of-pocket rule applies when a plaintiff can demonstrate that he paid money, and is now, out-of-pocket."). It is important to point out that Plaintiffs do not premise their standing on either of these two theories; indeed, Plaintiffs have neither alleged that Defendants somehow induced Plaintiffs to purchase the medications by misrepresenting or concealing any information, nor do Plaintiffs claim that the medications were ineffective for their prescribed use and that they paid a premium for the medications.

Instead, Plaintiffs claim that they were precluded from using the wasted eye drops because of Defendants' design of the bottle tip. But, what Plaintiffs do not allege, is that they were promised a specific number of doses or drops of the medications by Defendants and that they failed to receive those amounts. Absent any promises, Plaintiffs' theory of damages is merely "an unsupported conclusion concerning [their] alleged loss," *see Lieberson v. Johnson & Johnson Consumer Cos.*, 865 F. Supp. 2d 529, 541 (D.N.J. 2011); Plaintiffs do not allege what specific economic loss they have suffered. First, Plaintiffs do not allege any of the costs associated with the products at issue, and while Plaintiffs claim that the wasted drops have some economic value, they have failed to quantify that value. Put differently, Plaintiffs theorize that if the bottles were designed to dispense with smaller doses of eye drops, that fact would somehow produce a savings to them. Plaintiff's injury-related allegations amount

to nothing more than conjecture since Plaintiffs have neither alleged any comparable cheaper products that they would have purchased, nor have they alleged that Defendants would manufacture, or have manufactured, less expensive products based on a different design.

Notwithstanding those deficiencies, as to costs, Plaintiffs aver that "evidence" exists to establish that the medications at issue would be less expensive if the eye drops were made smaller. Plaintiffs cite to a 2006 article co-authored by an Allergan employee, which states that "smaller drops would be preferable to minimize systemic exposure and spilled or wasted medication" and reducing eye drop size would "provid[e] cost savings to patients and managed care providers." Compl., ¶ 7. Aside from the fact that this article presumably only pertains to Allergan's products, it is also cited out of context. The article discusses the possibility that patients might be able to dispense smaller drops from their ***existing*** bottles of medication by holding the bottle at a different angle. Crucially, there is no indication in the article that any of the defendants would manufacture products that produce smaller eye drops at a less expensive price.[5] Hence,

[5] Nor can Plaintiffs base their injury-in-fact on a statement that reducing drop size would result in Alcon selling fewer bottles of medication. Compl. ¶¶ 6, 79. Plaintiffs allege that such a statement was made by an unidentified Alcon marketing executive at an unspecified time for an unknown reason. But, this allegation does not meet the Rule 12(b)(6) standard as it is conclusory in

allegations based on this article are not sufficient to establish an injury-in-fact.

In sum, absent sufficient allegations as to injury, Plaintiffs are left with their bald assertion that they overpaid for effective eye medications that would have been less expensive if they were designed according to Plaintiffs' specifications. Such a conclusory theory is simply too remote and abstract to qualify as a concrete and particularized injury under Article III standing. *See, e.g.*, *Koronthaly*, 374 Fed. Appx. at 259 ("[a]bsent any allegation that [plaintiff] received a product that failed to work for its intended purposes or was worth objectively less than what one could reasonably expect," the plaintiff had not suffered Article III injury-in-fact); *Medley v. Johnson & Johnson Consumer Cos.*, No. 10-2291, 2011 U.S. Dist. LEXIS 4627, at *5-7 (D.N.J. Jan. 18, 2011) (plaintiffs lacked Article III standing because "the product worked as intended."); *Thompson*, 993 F. Supp. 2d at 1009 (rejecting claims similar to those raised here on the basis that plaintiffs failed to allege that the eye drop products are "anything other than what [they have] always purported to be" and received the "benefit of the bargain."); *Carter v. Alcon Labs, Inc.*, No. 13-997, 2014 U.S. Dist. LEXIS 32381, at *12-13 (E.D. Mo.

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nature. More importantly, this statement alone does not allege how it would impact Alcon's discretion, much less the discretion of the thirteen other Defendants, in setting the prices of redesigned products.

Mar. 13, 2014)("even if Defendants sold bottles with less medication, Plaintiff has not suggested there is anything to preclude them from charging what they now charge for the bottles currently available for purchase."); *Dominguez v. UAL Corp.*, 666 F.3d 1359, 1364 (D.C. Cir. 2012)(finding no Article III standing when plaintiffs' theory regarding United Airlines ticket prices required "pil[ing] speculation atop speculation" as to how United would price its tickets in the future); *Bowman v. RAM Med., Inc.*, 10-4403, 2012 U.S. Dist. LEXIS 75218, at *7-10 (D.N.J. May 31, 2012); *Waldron v. Jos. A. Bank Clothiers, Inc.*, No. 12-2060, 2013 U.S. Dist. LEXIS 189191, at *15 (D.N.J. Jan. 18, 2013); *Coghlan v. Wellcraft Marine Corp.*, 240 F.3d 449, 455 n.3 (5th Cir. 2001); *Medley v. Johnson & Johnson Consumer Cos.*, No. 10-2991, 2011 U.S. Dist. LEXIS 4627, at *4-6 (D.N.J. Jan. 18, 2011).[6]

Because Plaintiffs lack standing to bring suit, it deprives this Court of subject matter jurisdiction. *See Ballentine*, 486

[6] To be fair, I recognize that the court in *Eike v. Allergan, Inc.*, found that plaintiffs there, who brought claims similar to those asserted in this case, have sufficiently alleged an actual injury. 2014 U.S. Dist. LEXIS 34894, at *10-11 (S.D. Ill. Mar. 18, 2014). But, the *Eike* Court's analysis in that regard was confined to violations of the Illinois Consumer Fraud & Deceptive Business Practice Act, not Article III standing. More fundamentally, however, for the reasons expressed here, I am not persuaded by that court's conclusion. In fact, although I need not address the merits of Plaintiffs' claims, I note that the lack of Article III standing may be fatal to Plaintiffs establishing an ascertainable loss or injury in each of their state-law based consumer fraud claims.

F.3d at 810. Absent jurisdiction, it is well-settled that the Court is without authority to address the parties' remaining merit-based arguments. *See Adams v. Ford Motor Co.*, 653 F.3d 299, 304 (3d Cir. 2010) ("[i]f plaintiffs do not possess Article III standing, both the District Court and this Court lack subject matter jurisdiction to address the merits of plaintiff's case."). Nevertheless, because the Court finds that Plaintiffs have not sufficiently alleged standing, they are given leave to amend their Complaint to cure the deficiencies consistent with the dictates of this Opinion. Thus, I am not addressing the parties' arguments on the merits of Plaintiffs' case.[7]

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[7] I will nonetheless take this opportunity to highlight the issue of preemption should this litigation proceed farther - in the event the Complaint is amended and motion practice follows. Both Generic and Brand Name Defendants contend that Plaintiffs brought state law consumer fraud related claims in order to "force" the manufacturers to redesign their federally approved droppers to dispense smaller drops; doing so, Defendants submit, conflicts with federal law regulating manufacturers of prescription drugs. In the context of pharmaceutical regulations and specifically labeling, the Supreme Court in *Wyeth v. Levine*, 555 U.S. 555 (2009), held that the plaintiffs' labeling claims under state tort laws against ***brand name*** drug companies are not preempted by the FDCA. *Id.* at 578. However, in both *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), the Supreme Court held that state tort claims against ***generic*** companies - including labeling and design claims - are preempted because of the doctrine of "sameness." *See Mensing*, 131 S. Ct. at 2574-75; *Bartlett*, 133 S. Ct. at 2474-76. In so doing, the Supreme Court in these decisions made clear the distinction between generic and brand name products. It is, thus, incumbent upon the parties, here, to address any distinctions in future motion practice regarding preemption.

CONCLUSION

For the reasons set forth above, Defendants' motions to dismiss are **GRANTED** as Plaintiffs lack standing to bring suit. Plaintiffs are given leave to amend their Complaint within 30 days from the date of the Order accompanying this Opinion.

DATE: June 24, 2015

/s/ Freda L. Wolfson
United State District Judge